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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

08/463,987

06/05/1995

GEORGE GOICOECHEA

94-P0273US07

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54953

7590

05/24/2011

BROOKS, CAMERON & HUEBSCH, PLLC

1221 NICOLLET AVENUE

SUITE 500

MINNEAPOLIS, MN 55403

EXAMINER

SONNETT, KATHLEEN C

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

05/24/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

08/463,987

Applicant(s)

GOICOECHEA ET AL.

Examiner

KATHLEEN SONNETT

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2011.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54, 59, 62-64, 67 and 68 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 59, 63, 64, 67 and 68 is/are rejected.
7) ☒ Claim(s) 54 and 62 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 9/2/1997, 4/30/2001, 5/4/2009
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Terminal Disclaimer

1. The terminal disclaimer filed on 3/16/2011 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US 5,609,627 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Information Disclosure Statement

2. Applicant's arguments regarding the video cassette cited in the IDS submitted 4/30/2001 are moot as this video has been considered by the examiner. An initialed copy of the IDS filed 4/30/2001 has been attached to this document. Additionally, initialed copies of the IDS received on 9/2/1997 and 5/4/2009 have been attached. The three foreign documents which were lined through on the 1449 (IDS filed 8/20/2004) attached to the previous office action mailed 12/16/2010 will not be considered until an English language translation of these documents has been provided.

Claim Objections

3. Claims 54, 59, and 67 are objected to because of the following informalities:
- a. Claim 54: insert --a-- between "where" and "blood" in line 3.
 - b. Claim 59: insert --portion-- after "second distal stent" in line 7.
 - c. Claim 67: "at least one" should read "a" in line 8 since this limitation is only referring to the distal orifice of one of the intermediate stent portions. Each distal orifice receives only one second stent. Likewise, lines 9 and 10 should read "the second stent" and "the distal orifice".
 - d. Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. **Claims 59, 63, 64, 67, and 68** rejected under 35 U.S.C. 103(a) as being unpatentable over Martin (US 5,575,817) in view of Lassiter et al. (US 1,417,393; "Lassiter"). Regarding claim 59, Martin discloses a bifurcated prosthesis for use near an aneological bifurcation of a blood vessel into two branched vessels comprising a bifurcated stent having a bifurcated proximal stent portion (1) adapted to be disposed within the blood vessel, a first distal stent portion (4) adapted to extend across the bifurcation into one of the branched vessels, and a second distal stent portion (5) shorter than the first distal stent portion and configured to be disposed entirely within the blood vessel, and a graft layer formed from a biocompatible fabric disposed in juxtaposition with the bifurcated stent (see entire document, esp. figs. 1-4). The second distal stent comprises a distal orifice at a distal end of a portion which when expanded serves to receive a male engaging portion of an additional stent (2) completely within a female engaging portion of the distal orifice. Martin does not expressly disclose that the second distal stent's orifice is at the end of a tapering portion which forms a female engaging portion that receives the frustoconical male engaging portion of the additional stent.

6. Lassiter discloses another apparatus comprising tubular elements joined together to form a fluid flow path which includes a tube having a male engaging portion that fits within the female engaging portion of second tube. The male engaging portion of the first tube is frustoconically shaped and is received completely within a tapered, female engaging portion of the distal orifice of the second tube as shown in fig. 15. Lassiter teaches that the use of a tapering

female engaging portion and frustoconically shaped male engaging portion is advantageous because it allows a mechanical interlock between the two tubes to be provided which reinforces the connection between the two tubes and tends to prevent possible separation of parts under strains and thus adds to the security of the connection (page 3, lines 93-113). It would have been obvious to one skilled in the art to have modified the device of Martin to include a tapered portion as taught by Lassiter at the distal end of the second distal stent portion (5) which receives stent (2) in order to reinforce the friction-fit connection formed between the two stents. It is noted that it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the prior art of Lassiter is reasonably pertinent to the particular problem of forming a reliable, secure connection between the male and female connecting portions of two fluid carrying conduits.

7. Regarding claim 63, Martin discloses a method for delivering a stent to an angiological bifurcation of a vessel comprising placing in the vessel a first bifurcated stent (1) having at least one leg (5) disposed entirely within the vessel and attaching to the leg disposed entirely within the vessel a second stent (2) that extends into one of the two branched vessels (see entire document). The bifurcated stent of Martin has a distal orifice at a distal end of a female engaging portion of the at least one leg which, when expanded, serves to receive a male engaging portion. As discussed above, Lassiter makes obvious tapering the female and male engaging portions in order to improve the security of the connection. This tapering results in a frustoconically shaped male portion received completely within the female engaging portion.

8. Regarding claim 64, the step of placing the first bifurcated stent further comprises extending a leg (4) of the first bifurcated stent into one of the two branched vessels.

9. Regarding claim 67, the bifurcated stent comprises a proximal stent portion and two intermediate stent portions extending distally relative to the assembly bifurcation and a second stent (2) joined to one (5) of said intermediate stent portions and adapted to allow blood to flow from the proximal stent portion of the bifurcated stent into one of the branched vessels. At least one of the intermediate stent portions has a distal orifice at a distal end of a female engaging portion of the distal orifice which, when expanded, serves to receive a male engaging portion of the second stent. As discussed above, Lassiter makes obvious tapering the female and male engaging portions in order to improve the security of the connection. This tapering results in a frustoconically shaped male portion received completely within the female engaging portion.

10. Regarding claim 68, stent portion (2) is mated to the second distal stent portion (5) and includes a graft layer formed from a biocompatible fabric disposed in juxtaposition with it and adapted to allow blood to flow from the bifurcated proximal stent portion into the other branched vessel.

Allowable Subject Matter

11. Claims 54 and 62 are objected to for the minor typographical error in claim 54 mentioned above but would be allowable upon correction of this minor informality.

Response to Arguments

12. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHLEEN SONNETT whose telephone number is (571)272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 5/20/2011
/Kathleen Sonnett/
Primary Examiner, Art Unit 3731